

Dated: November 17, 2006.
Stephen F. Sundlof,
 Director, Center for Veterinary Medicine.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use in Animal Feeds; Florfenicol

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Schering-Plough Animal Health Corp. The NADA provides for the use of a florfenicol Type A medicated article by veterinary feed directive to formulate swine feed used for the control of respiratory disease.

DATES: This rule is effective December 4, 2006.

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7571, e-mail: joan.gotthardt@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 556 Morris Ave., Summit, NJ 07901, filed NADA 141-264 that provides for use of NUFLOL (florfenicol), an antibiotic, a Type A medicated article by veterinary feed directive to formulate Type C medicated feeds used for the control of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Streptococcus suis*, and *Bordetella bronchiseptica* in groups of swine in buildings experiencing an outbreak of SRD. The NADA is approved as of November 3, 2006, and the regulations are amended in 21 CFR 558.4 and 558.261 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning November 3, 2006.

The agency has determined under 21 CFR 25.33(d)(5) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

2. In paragraph (d) of § 558.4, in the "Category II" table, revise the entry for "Florfenicol" to read as follows:

§ 558.4 Requirement of a medicated feed mill license.

* * * * *

(d) * * *

CATEGORY II

Drug	Assay limits percent ¹	Type A	Type B maximum (100x)	Assay limits percent ¹	Type B/C ²
Florfenicol	*	90-110	Swine feed: n/a Catfish feed: n/a	*	Swine feed: 85-115 Catfish feed: 80-110
	*	*	*	*	*

¹Percent of labeled amount.

²Values given represent ranges for either Type B or Type C medicated feeds. For those drugs that have two range limits, the first set is for a Type B medicated feed and the second set is for a Type C medicated feed. These values (ranges) have been assigned in order to provide for the possibility of dilution of a Type B medicated feed with lower assay limits to make Type C medicated feed.

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3. In § 558.261, revise paragraphs (a) and (c)(2); redesignate paragraph (e)(1) as paragraph (e)(2); and add new paragraphs (c)(3) and (e)(1) to read as follows:

§ 558.261 Florfenicol.

(a) *Specifications.* Type A medicated articles containing florfenicol in the following concentrations:

(1) 40 grams per kilogram for use as in paragraph (e)(1) of this section.

(2) 500 grams per kilogram for use as in paragraph (e)(2) of this section.

* * * * *

(c) * * *
 (2) The expiration date of veterinary feed directives (VFDs) for florfenicol medicated feeds:

(i) For catfish must not exceed 15 days from the date of issuance;

(ii) For swine must not exceed 90 days from the date of issuance.

(3) VFDs for florfenicol shall not be refilled.

* * * * *

(e) * * *

(1) *Swine—(i) Amount.* Feed 182 grams per ton of feed (200 parts per million) continuously as the sole ration for 5 days.

(ii) *Indications for use.* For the control of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Pasteurella multocida*, *Streptococcus suis*, and *Bordetella bronchiseptica* in groups of swine in buildings experiencing an outbreak of SRD.

(iii) *Limitations.* The safety of florfenicol on swine reproductive performance, pregnancy, and lactation

has not been determined. Feeds containing florfenicol must be withdrawn 13 days prior to slaughter.

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Dated: November 17, 2006.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[USCG-2001-10881]

RIN 1625-AA36

Drawbridge Operation Regulations; Amendment

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard revises its drawbridge regulations by lengthening the period for which a deviation from published bridge opening requirements is authorized, and by reorganizing and clarifying some provisions. These changes promote intermodal mobility, safety, and security while balancing the reasonable needs of land and marine traffic.

DATES: This rule is effective January 3, 2007.

ADDRESSES: Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG-2001-10881 and are available for inspection or copying at the Docket Management Facility, U.S. Department of Transportation, room PL-401, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet at <http://dms.dot.gov>.

FOR FURTHER INFORMATION CONTACT: Mr. Chris Jaufmann, Office of Bridge Administration, United States Coast Guard Headquarters, 202-372-1511. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Dockets Operations, Department of Transportation, telephone 202-493-0402.

SUPPLEMENTARY INFORMATION:

Regulatory History

On April 17, 2003, we published a notice of proposed rulemaking (NPRM)

for this rulemaking (68 FR 18922). We received 11 letters commenting on the NPRM. All comments were addressed in a supplemental notice of proposed rulemaking (SNPRM) published in the **Federal Register** on May 17, 2006 (71 FR 28629). No comments were received regarding the SNPRM. No public meeting was requested and none was held.

Background and Purpose

The last major update to the drawbridge regulations in 33 CFR Part 117 was in 1984. The Coast Guard determined that updates and clarifications to the present regulations are necessary to meet the competing needs of land and navigational traffic as well as meeting the needs of bridges that have become structurally deficient and functionally obsolete.

Discussion of Changes

The changes made by this final rule are grouped by subject and discussed below.

Deviations

At present, the Coast Guard has two deviations that allow bridge owners to change operating schedules for 60 days for maintenance and repair needs, and up to 90 days to test a new operating schedule. In our final rule, we are consolidating all temporary changes to a drawbridge operating schedule into one of two categories: (1) A deviation, when the temporary change will be for a period of 180 days or less, or; (2) a rulemaking, when the temporary change will be for a period greater than 180 days. This change amends § 117.35 and removes §§ 117.37, 117.43, and 117.45.

This deviation provision would allow the District Commanders the flexibility to maximize waterway use for navigation prior to and during varying weather conditions, repair/maintenance situations, reasons of public health and safety and public events. Any temporary change of an operating schedule lasting greater than 180 days or any permanent change to an operating schedule will require a full rulemaking under the Administrative Procedure Act. This will not affect the bridge owners' responsibility to notify the Coast Guard in a timely manner with their request to change an operating schedule or the discretion of the District Commander to accept the request.

Bridge Owner Responsibility

We are changing the requirements in § 117.7 to clarify the bridge owner's responsibility in maintaining their drawbridges in operable condition.

Appendix A

In the NPRM, the Coast Guard proposed to remove Appendix A to 33 CFR 117 "Drawbridges Equipped with Radiotelephones". Appendix A provided information that is already contained in other sources and does not need to be repeated in 33 CFR 117. No comments were received regarding this issue so Appendix A is removed. However, the information formerly contained in Appendix A is available on the Bridge Administration (G-PWB) Web site, <http://www.uscg.mil/hq/g-o/g-opt/g-opt.htm>, and also in the National Oceanographic and Atmospheric Administration's (NOAA) nine volume publication of the "United States Coast Pilot" or on NOAA's Web site. We are also removing a note in § 117.15 that referenced Appendix A.

Definitions

The Coast Guard is adding eight definitions in Subpart A to be used throughout part 117. These definitions clarify the terms "Automated drawbridge", "Deviation", "Drawbridge", "Drawspan", "Public vessel", "Remotely operated drawbridge", "Removable drawspan bridge", and "Untended" in this part. We also reworded the four definitions currently in § 117.4 for plain language.

Lindsey Slough

The Coast Guard is removing the word "maintenance" from § 117.165 thereby requiring any vessel wanting to pass through the removable span bridge, across Lindsey Slough, to give a 72-hour advance notice.

The bridge was constructed in the 1960s and the permit to build the bridge dictated that the drawbridge open for maintenance vessels. A final rule setting a time requirement of 72 hours advance notice for passage was published in the **Federal Register** on April 24, 1984 (49 FR 17452). At the time of publication, the primary focus was on access for maintenance barges and the term maintenance was included in the rule. However, the removable span has never been removed for any vessel and to do so would require a barge with a crane to be brought in to remove the span. Because the bridge has not had a request to open since 1984, the requirement for all vessels to provide 72-hours advance notice will meet the reasonable needs of navigation and will not cause any undue burden on navigation.

Clarifications

The Coast Guard is adding three new sections to clarify existing requirements in part 117. We are adding § 117.8 to explain how to request a permanent